

NOVEL DRUG APPROVALS 2018

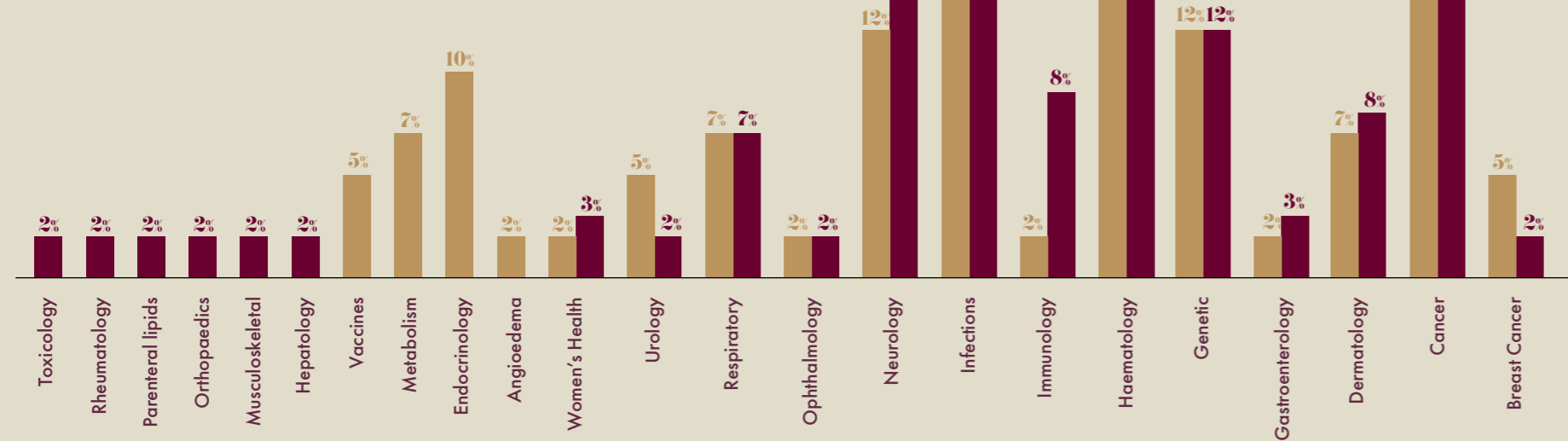
EMA & FDA APPROVALS BY THERAPEUTIC AREA

2018 was a remarkable year for industry R&D. The FDA approved 59 new molecular entities (NMEs), breaking the 1996 record of 50 approvals, while the EMA suggested 84 new medicines for EU approval, 42 of these being new active substances (NASs), compared with 35 NAS.

This infographic provides an overview of the NMEs/NASs that were approved/recommended for approval by both associations in 2018.

● EMA-approved
● FDA-approved

Source: EMA, 2018 & FDA, 2018



FUN FACT!

Haemophilia-targeting drugs were the most frequently approved in both EMA and

FDA, making up **27%** and **41%**, respectively, of the cancer drugs approved.

NOTABLE DRUGS APPROVED IN 2018

Women's Health

Orilissa (AbbVie)

This is the first new treatment in 10 years to manage the pain associated with endometriosis, a condition affecting 1 in 10 women during their reproductive years. A wellness tracking, free, life app developed by AbbVie accompanies the prescribed medication.

Infections

Tpoxx (SIGA Technologies Inc.)

This is the first drug with an indication for treatment of patients with smallpox. Even though the WHO declared global eradication of the disease in 1980, there have been concerns of the use of smallpox in biological warfare, so this approval marks a significant milestone.

Neurology

Aimovig (Amgen & Novartis)

This new class of migraine medications works by blocking the activity of calcitonin gene-related peptide (CGRP), a molecule that is involved in migraine attacks. Aimovig is the first human monoclonal antibody therapy for migraine prevention to be approved.

Cancer, Haemophilia

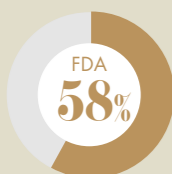
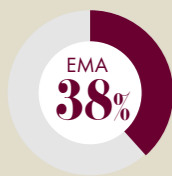
Kymriah (Novartis) & Yescarta (Kite Pharma)

The first two CAR T-cell therapies in the EU intended for the treatment of certain blood cancers, they are also the first medicines supported through the EMA's Priority Medicines (PRIME) scheme. Belonging to a new generation of personalised cancer immunotherapies, CAR T therapy harnesses and modifies a patient's own T cells.

ORPHAN APPROVALS BY THERAPEUTIC AREA 2018

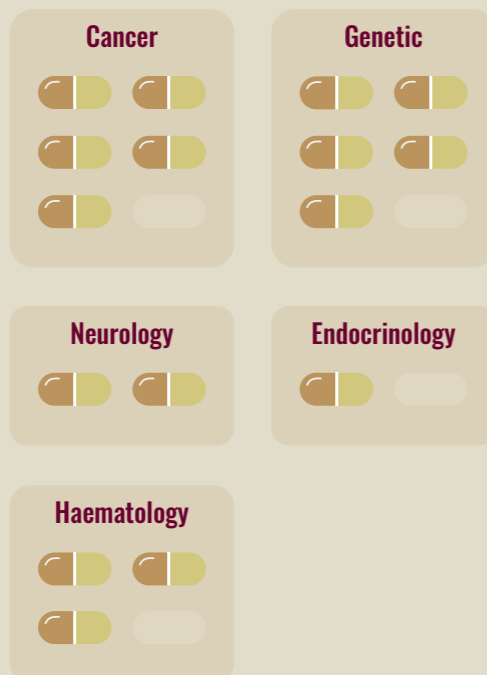
Orphan drugs capture a large number of drugs approved or recommended. Orphan drugs are synonymous with diseases of a high unmet need, exemplifying how 2018 was a banner year for R&D innovation.

% OF ORPHAN DRUGS APPROVED IN 2018 BY THE:



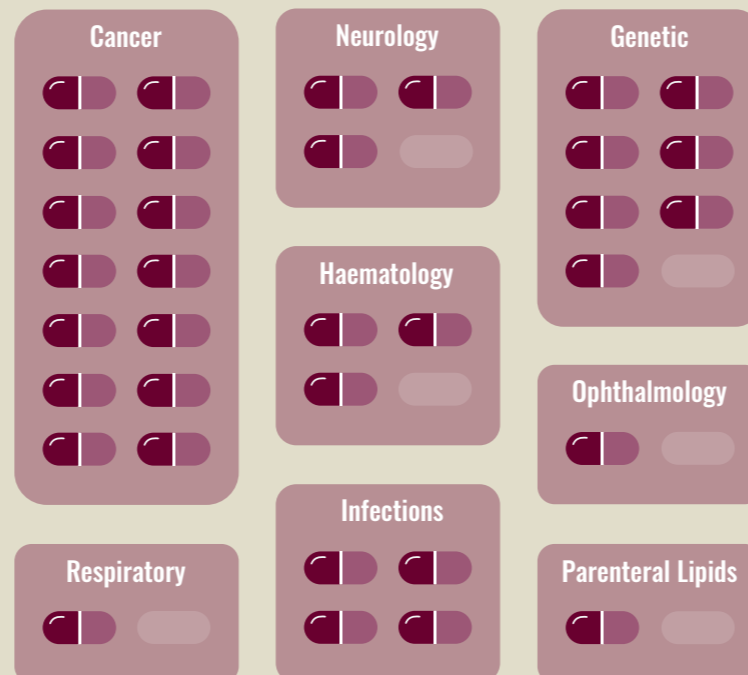
EMA-APPROVED ORPHAN DRUGS IN 2018

One pill = one orphan drug approved

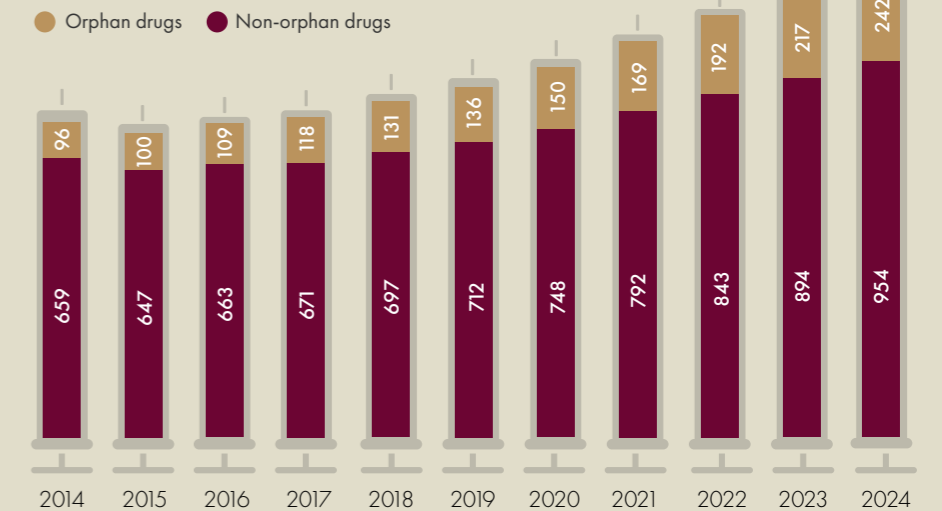


FDA-APPROVED ORPHAN DRUGS IN 2019

One pill = one orphan drug approved



WORLDWIDE DRUG SALES (billions \$)



PREDICTED SALES GROWTH RATE 2014-2024

+58.4% Non-orphan & orphan drugs | +44.8% Non-orphan | +152.1% Orphan